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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/829,079	04/22/2004	Stephen Bennett Elliott		6024

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EXAMINER

KAHELIN, MICHAEL WILLIAM

ART UNIT PAPER NUMBER

3762

DATE MAILED: 11/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/829,079		ELLIOTT, STEPHEN BENNETT	
	Examiner		Art Unit	
	Michael Kahelin		3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Claims 1-18 are rejected as failing to define the invention in the manner required by 35 U.S.C. 112, second paragraph.

The claim(s) are narrative in form and replete with indefinite and functional or operational language. The structure which goes to make up the device must be clearly and positively specified. The structure must be organized and correlated in such a manner as to present a complete operative device. Note the format of the claims in the patent(s) cited.

4. In regards to claims 3-16, the active voice, as opposed to the passive voice, should be used. For instance, in claim 3, "feedback...is provided". The method steps must be actively recited, such as "the method of claim 1 wherein facilitating the synchronization of the varying breathing cycle with the varying heart rate variability cycle comprises providing feedback..." Examiner has interpreted the claims as being actively recited and should be amended accordingly.

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5. In regards to claims 2, 4, 6, 8, 10, 12, 14, 15, and 16, the elements of an apparatus must be positively recited before being further limited. These apparatus claims merely recite functional limitations, rendering them vague because it is unclear whether these are system (apparatus) claims or method claims. It is suggested to first positively recite components of the system before further limiting them. For instance, claim 1 could read: "A system for achieving coherence of the heart rate variability cycle during exercise comprising a means for facilitating the synchronization..."

6. In regards to claims 11, 12, 13 and 14, the limitations of "said tempo generation" and "what feedback" are lacking antecedent basis. Because there is no mention of these elements in claims 1 or 2, they cannot be further limited. It is suggested to first positively recite these elements before limiting them further. Examiner is interpreting the elements as having been positively recited and should be amended accordingly.

7. In regards to claim 16, "etc." renders the claim vague because the metes and bounds of the claim are unclear. It is suggested to list only those embodiments for which patent protection is sought.

8. In regards to claims 17 and 18, the claims are omnibus type claims. The phrase "present invention" is vague because it is unclear as to what metes and bounds this encompasses. Examiner has interpreted "present invention" as being the limitations as set forth in claim 1.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-6 and 9-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Vaschillo et al. (5,997,482).

11. In regards to claims 1 and 2, Vaschillo et al. disclose a device/method that facilitates the synchronization of the breathing and heart rate cycles (abstract).

12. In regards to claims 3, 4, 5, and 6, feedback is provided as to when to begin inhalation and exhalation based on peak positive and negative heart rate (col. 3, line 23).

13. In regards to claims 9 and 10, a fully variable tempo of the heart rate variability and breathing is provided (Fig. 2). Examiner is interpreting physical motion as voluntary breathing.

14. In regards to claims 11 and 12, the subject can optimize the rate of physical motion. Because there is nothing preventing physical motion in Vaschillo et al.'s disclosure, the subject is free to optimize their rate of physical motion any way they deem fitting.

15. In regards to claims 13 and 14, the user can select multiple forms of feedback (col. 7, line 15).

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16. In regards to claims 15 and 16, the device is instantiated in hardware (Fig. 2), which is a physical form.
17. In regards to claim 17, the method is applied to a therapeutic modality (Claim 1).
18. In regards to claim 18, the method is applied to a human subject (Title).

Claim Rejections - 35 USC § 103

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vaschillo et al. in view of Sackner et al. (6,047,203). Vaschillo et al. disclose the essential features of the claimed invention except for enabling and disabling feedback based on heartbeat rate stability. Sackner et al. teach of a physiological feedback device that enables or disables a message on the basis of heartbeat rate stability (col. 6, line 39) to allow the user to take action based on heartbeat rate stability. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Vaschillo et al.'s invention by providing feedback that is enabled or disabled based on heart beat variability to allow the user to take action based on heartbeat rate stability.

Response to Arguments

20. Applicant's arguments filed 10/24/2005 have been fully considered but they are not persuasive. Applicant's arguments are that the intended use of Vaschillo et al.'s invention differs between Applicant's; that Vaschillo et al.'s invention facilitates resonance, while Applicant's facilitates synchrony; and that Vaschillo et al.'s invention is not used during exercise. Although the intended use and intended results are disclosed by Applicant in the "Specification" section of the patent application, the sole determinant of patentability is the claim language. The system claims must contain concrete structural elements and relationships and the method claims must contain concrete method steps that are both unanticipated and unobvious over the prior art to be patentable. Additionally, the claim language of the application must be read in its

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"broadest reasonable sense". For instance, claim 1 recites that Applicant's invention is to be used during exercise. Vaschillo et al.'s system allows the subject to achieve coherence between the breathing cycle and heart beat cycle, and is inherently capable of being used during exercise, considering that the act of breathing can be interpreted to be exercise in its "broadest reasonable sense", so it meets the claim language. Lastly, intended use is usually not given patentable weight. So, although Applicant argued that Vaschillo et al.'s invention is used for relaxation, while Applicant's is used for synchronizing breathing with motion and heart rate, Vaschillo et al.'s invention is capable of performing the claimed method and meets the limitations of the claimed system. It is very important to reiterate that the test for patentability lies almost entirely in the claims and, since the references above meet the claim limitations, the claims are still rejected under 35 U.S.C. 102, and 103, as indicated above. In addition, the rejections under 35 U.S.C. 112(2) remain unresolved and stand.

21. This action is a **final rejection** and is intended to close the prosecution of this application. Applicant's reply under 37 CFR 1.113 to this action is limited either to an appeal to the Board of Patent Appeals and Interferences or to an amendment complying with the requirements set forth below.

If applicant should desire to appeal any rejection made by the examiner, a Notice of Appeal must be filed within the period for reply identifying the rejected claim or claims appealed. The Notice of Appeal must be accompanied by the required appeal fee of \$250.00.

If applicant should desire to file an amendment, entry of a proposed amendment after final rejection cannot be made as a matter of right unless it merely cancels claims or complies with a formal requirement made earlier. Amendments touching the merits of the application which otherwise might not be proper may be admitted upon a showing a good and sufficient reasons why they are necessary and why they were not presented earlier.

A reply under 37 CFR 1.113 to a final rejection must include the appeal from, or cancellation of, each rejected claim. The filing of an amendment after final rejection, whether or not it is entered, does not stop the running of the statutory period for reply to the final rejection unless the examiner holds the claims to be in condition for allowance. Accordingly, if a Notice of Appeal has not been filed properly within the period for reply, or any extension of this period obtained under either 37 CFR 1.136(a) or (b), the application will become abandoned.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Kahelin whose telephone number is (571) 272-8688. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MWK



GEORGE R. EVANISKO
PRIMARY EXAMINER

11/4/5